REMARKS

This responds to the Office Action dated March 25, 2008.

No claims are amended. No claims are canceled. No claims are added. As a result, claims 41-48 are now pending in this application.

Telephonic Interview Summary

Applicant thanks Examiner George Evanisko for extending the courtesy of a telephonic interview with Applicant's representative Edward Sandor on June 25, 2008 to discuss Applicant's proposed amendment and response of June 25, 2008, where Examiner Evanisko and Applicant's representative discussed the proposed amendment and response in relation to the cited art. Further, Applicant's representative and Examiner Evanisko discussed filing a declaration under 37 C.F.R. § 1.131 to antedate the Musley et al. (U.S. 2004/0210256) reference.

Request for Telephonic Interview

In the event that this response does not render all claims allowable, Applicant's representative, Edward Sandor, respectfully formally requests a further telephonic interview with the Examiner upon receipt of this response, in order to carry out telephonic prosecution of this patent application to mutually facilitate and expedite the examination. Applicant's representative, Edward Sandor, can be reached by telephone at 612-371-2174.

§103 Rejection of the Claims

1. Claims 41 and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Musley et al. (U.S. 2004/0210256) in view of Tacker, Jr. et al. (U.S. Patent No. 6,006,132). Applicant respectfully traverses.

a. Applicant respectfully submits that no *prima facie* case of obviousness presently exists with respect to these claims because all elements are not present in the cited references or the reasoning set forth in the Office Action.

Applicant cannot find, in the cited portions of the cited references, any disclosure, teaching, or suggestion of a handheld patient-operated user-interface device configured to provide, in response to a therapy request command, a normal rhythm indication if the heart rhythm status information is indicative of a normal heart rhythm, an abnormal rhythm indication if the heart rhythm status information is indicative of an abnormal heart rhythm, a therapy pending indication if the heart rhythm status information is indicative of an abnormal heart rhythm that can be treated by the implantable cardiac rhythm management device, a contact caregiver indication if the heart rhythm status information is indicative of a condition requiring the intervention of a physician, and configured to deliver a therapy if the therapy pending indication is provided in response to the therapy request command, as currently recited or similarly incorporated in the present claims.

Regarding Musley et al., the Office Action states that,

> Musley et al discloses the claimed invention as a patient activator having heart rhythm status information such as normal rhythm, abnormal rhythm, therapy pending and contact caregiver indicators (e.g. figure I, paragraph 40), receiving and displaying the information, and use of a therapy request button to deliver therapy and indicate therapy is pending. Musley does not disclose that it is a handheld device and that in response to the therapy request that the heart rhythm status information is provided.

(Office Action at pages 2-3.) Regarding Tacker, Jr. et al., the Office Action states that,

> Tacker teaches that it is known to use a handheld activator and to provide the heart rhythm status information in response to the therapy request to provide a device that the patient can easily carry and use and to allow the patient to reconfirm the arrhythmia before the therapy is delivered and to provide the patient with updated status information based on the therapy request (e.g. col 8, lines 22-40).

(Office Action at pages 2-3.) However, the cited portions of Tacker, Jr. et al. merely state that,

> If the patient is in atrial fibrillation, the defibrillator will not go directly to provision of cardioversion therapy. Instead, it is up to the patient whether or not cardioversion will take place at that time. Here, the audible voice message played back by the device 110 may prompt the patient to further action. That further action may be to reprogram the defibrillator into the patient activated mode by using switch 118 and then to depress switch 120 to transmit another sequence command. Alternatively, the defibrillator may be programmed so that reprogramming would not be necessary and only requiring switch 118 to be depressed again to initiate therapy. With either approach, *it is preferred and*

> *desirable, although not absolutely necessary, to repeat atrial fibrillation detection before the attempted cardioversion. Of course, at each stage of the redetection and cardioversion process, suitable status messages may be generated for audible speech playback by device 110 to keep the patient informed.*

(Tacker, Jr. et al. at col. 8, lines 22-40, emphasis added.) Applicant respectfully submits that Tacker, Jr. et al. merely discloses repeating atrial fibrillation detection before an attempted cardioversion. As such, Applicant respectfully submits that the cited references do not disclose, teach, or suggest a handheld patient-operated user-interface device configured to provide, in response to a therapy request command, a normal rhythm indication if the heart rhythm status information is indicative of a normal heart rhythm, an abnormal rhythm indication if the heart rhythm status information is indicative of an abnormal heart rhythm, a therapy pending indication if the heart rhythm status information is indicative of an abnormal heart rhythm that can be treated by the implantable cardiac rhythm management device, a contact caregiver indication if the heart rhythm status information is indicative of a condition requiring the intervention of a physician, and configured to deliver a therapy if the therapy pending indication is provided in response to the therapy request command, as currently recited or similarly incorporated in the present claims.

Because Musley et al., Tacker, Jr. et al., and/or the reasoning set forth in the Office Action fail to set forth all elements recited or incorporated in claims 41 or 46, Applicant respectfully submits that there is no *prima facie* case of obviousness with respect to these claims. Therefore, Applicant respectfully requests reversal of this basis of rejection for said claims.

b. Separately, as to Musley et al., Applicant respectfully submits herewith a declaration of inventor Jay W. Axelrod under 37 C.F.R. § 1.131 antedating the Musley et al. reference, including the required showing under 37 C.F.R. § 1.131. Applicant respectfully submits that the subject matter of the present claims was reduced to practice prior to April 17, 2003, the filing date of the Musley et al. reference, as evidenced by the attached redacted photocopies of signed notebook pages (Exhibit A) and the attached redacted photocopies of the signed invention disclosure form (Exhibit B). As such, Applicant respectfully submits that Musley et al. is disqualified as a prior art reference under 35 U.S.C. § 102(a), and respectfully submits that the rejection of claims 41 and 46 have been obviated because Tacker, Jr. et al. and/or the reasoning

set forth in the Office Action fail to set forth all of the elements recited or incorporated in claims 41 and 46. Accordingly, Applicant respectfully requests reversal of this basis of rejection for said claims.

2. Claims 42-45, 47 and 48 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Musley et al. in view of Tacker, Jr. et al. as applied to claims 41 and 46 above. Applicant respectfully traverses.

a. First, the Office Action admits that the elements of claims 42-45 and 47-48 are not shown in the cited references. (*See* Office Action at page 3.)

The Office Action states that having a stop therapy button is known in the art. (*See* Office Action at pages 3-4.) However, the Office Action has failed to show a user-interface device configured to deliver a stop therapy request to a cardiac rhythm management device and the cardiac rhythm management device configured to stop a therapy in response to the stop therapy request in combination with the elements in the base claim.

Further, the Office Action states that having deadfront status indicator is known in the art, stating that,

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cardiac system and method as taught by Musley in view of Tacker and the interface device . . . having deadfront status indicators each with different pictorial graphic shapes, such as a green colored heart shape, orange colored icon in a heart shape with a clock face, a yellow colored icon in the shape of a heart with a sharp jagged line extending across the heart, and a red colored icon in the shape of a telephone having a base unit with a cross in the center of the base unit, to provide the predictable results of: allowing the operator to use their visual sense to determine the status of the device which can aid in noisy environments; allowing the device to clearly indicate the status to allow the operator to easily distinguish between different conditions; allowing caregivers to more quickly and efficiently perform the required steps or to allow caregivers not familiar with that country's language/text to still operate the device and perform the correct steps.

(*Id.*) Applicant respectfully submits that the claimed selection of particular pictorial indicators (i.e., "normal rhythm," "contact caregiver," "therapy pending," and "abnormal rhythm") are inventive in that they have been carefully selected to most effectively provide information to a

target patient population that often tends to be elderly, in ill-health, and sometimes easily confused. Further, Applicant respectfully submits that the specific combination of shapes and colors have been carefully selected to most effectively provide the necessary information. Applicant does not disagree with the many advantages of the current claims identified by the Office Action. However, the Office Action fails to show a reference that even suggest using deadfront status indicators to illustrate heart rhythm status information to a user. Instead, the Office Action relies on hindsight to show advantages of Applicant's combination, and then uses the advantages to reject Applicant's claims. Applicant respectfully submits that the Office Action improperly deconstructed Applicants claimed invention into various individual elements that—when properly analyzed in combination and as a whole, provide an extremely clinically useful device for a vulnerable patient population, and then used the usefulness itself to improperly reject the claims. Moreover, Accordingly, because no *prima facie* case of obviousness presently exists with respect to these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Lastly, the Office Action states, in contradiction to the Office Action's reasoning set forth above, that

> In addition, the use of the different shapes, such as set forth in claims 45 and 48, does not patentably distinguish or is of patentable significance over the system and method of Musley in view of Tacker since it is an arbitrary/aesthetic design consideration that is obvious to one having ordinary skill in the art (see MPEP 2144.04).

(*Id.*) Applicant respectfully traverses, and submits that merely lines above the Office Action's assertion that the deadfront status indicators are an arbitrary/aesthetic design consideration, the Office Action listed numerous clinical advantages for having the different shapes and colors. Moreover, Applicant submits that the shapes and colors used are not arbitrary or an aesthetic design consideration, but serve the functional purpose of effectively providing necessary information to a vulnerable patient population. Accordingly, because no *prima facie* case of obviousness presently exists with respect to

these claims, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

b. Separately, as to Musley et al., Applicant respectfully submits herewith a declaration of inventor Jay W. Axelrod under 37 C.F.R. § 1.131 antedating the Musley et al. reference, including the required showing under 37 C.F.R. § 1.131. Applicant respectfully submits that the subject matter of the present claims was reduced to practice prior to April 17, 2003, the filing date of the Musley et al. reference, as evidenced by the attached redacted photocopies of signed notebook pages (Exhibit A) and the attached redacted photocopies of the signed invention disclosure form (Exhibit B). As such, Applicant respectfully submits that Musley et al. is disqualified as a prior art reference under 35 U.S.C. § 102(a), and respectfully submits that the rejection of claims 42-45, 47 and 48 have been obviated because Tacker, Jr. et al. and/or the reasoning set forth in the Office Action fail to set forth all of the elements recited or incorporated in claims 42-45, 47 and 48. Accordingly, Applicant respectfully requests reversal of this basis of rejection for said claims.

Reservation of Rights

In the interest of clarity and brevity, Applicant may not have equally addressed every assertion made in the Office Action, however, this does not constitute any admission or acquiescence. Applicant reserves all rights not exercised in connection with this response, such as the right to challenge or rebut any tacit or explicit characterization of any reference or of any of the present claims, the right to challenge or rebut any asserted factual or legal basis of any of the rejections, the right to swear behind any cited reference such as provided under 37 C.F.R. § 1.131 or otherwise, or the right to assert co-ownership of any cited reference. Applicant does not admit that any of the cited references or any other references of record are relevant to the present claims, or that they constitute prior art. To the extent that any rejection or assertion is based upon the Examiner's personal knowledge, rather than any objective evidence of record as manifested by a cited prior art reference, Applicant timely objects to such reliance on Official Notice, and reserves all rights to request that the Examiner provide a reference or affidavit in

support of such assertion, as required by MPEP § 2144.03. Applicant reserves all rights to pursue any cancelled claims in a subsequent patent application claiming the benefit of priority of the present patent application, and to request rejoinder of any withdrawn claim, as required by MPEP § 821.04.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's representative at (612) 371-2174 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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Date July 23, 2008 By _____
Edward J. Sandor
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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being filed using the USPTO's electronic filing system EFS-Web, and is addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 23 day of June, 2008.

KATE GANNON _____
Name Signature